A rejection under <u>35 U.S.C. 102(b)</u> cannot be overcome by affidavits and declarations under <u>37 CFR 1.131</u>

(Rule 131 Declarations), foreign priority dates, or evidence that applicant himself invented the subject matter. Outside the 1-year grace period, applicant is barred from obtaining a patent containing any anticipated or obvious claims. *In re Foster*, 343 F.2d 980, 984, 145 USPQ 166, 170 (CCPA 1965).

As can be seen, this MPEP passage relates to a completely irrelevant issue, i.e., whether an applicant's own disclosure of her own invention can be eliminated as a "statutory bar" when such disclosure is in a published document more than one year prior to the filing of an application. Under such circumstances, of course, the examiner is correct: An applicant's own published disclosure of her own invention more than one year prior to filing a patent application cannot be overcome by an affidavit or declaration. In addition, as the second portion of the MPEP passage states, Rule 131 declarations also cannot be used where the published disclosure involves the invention of a third party. That is, applicants cannot "swear back" of any invention which is effective as prior art under 35 USC 102(b).

However, this MPEP section is completely irrelevant to the issue at hand. The Sekiguchi declaration here is, of course, not being offered as a Rule 131 declaration. Rather, it is a Rule 132 declaration which establishes that the published Sekiguchi Japanese applications are not anticipatory because they do not satisfy the US law requirement that an anticipatory reference be enabling.

That declarations can be filed for the purpose of showing that an allegedly anticipatory reference is not enabling (and thus not effectively anticipatory) is clear from the MPEP. See the following passage from MPEP 2121.01:

2121.01 Use of Prior Art in Rejections Where Operability Is in Question [R-3]

3

"In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention 'not novel' or 'anticipated' within section 102, the stated test is whether a reference contains an 'enabling disclosure'...." *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description

ELLIS-0003

of the subject matter is insufficient, if it cannot be produced without undue experimentation. Elan Pharm., Inc. v. **>Mayo Found. For Med. Educ. & Research<, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003) (At issue was whether a prior art reference enabled one of ordinary skill in the art to produce Elan's claimed transgenic mouse without undue experimentation. Without a disclosure enabling one skilled in the art to produce a transgenic mouse without undue experimentation, the reference would not be applicable as prior art.). A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." In re Donohue, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985).

See also the following relevant excerpt from MPEP 716.07:

716.07 Inoperability of References

Affidavits or declarations attacking the operability of a patent cited as a reference must rebut the presumption of operability by a preponderance of the evidence. *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980).

Thus, because the Sekiguchi declaration is being filed under Rule 132 and not under rule 131, it is perfectly acceptable for the purpose for which it is offered, i.e., to provide sufficient evidence that the two cited Japanese publications of Professor Sekiguchi are not anticipatory because they are not enabling.

Request for Clarification

In the office action of November 21, 2005 (pages 2 and 3), the examiner stated: "Applicants have submitted a letter establishing the deposited antibodies reported in the Japanese patent do not bind the ED-B domain of fibronectin..." The undersigned takes this statement at face value, i.e., as an indication that the examiner considers the facts established by the Sekiguchi declaration as effectively showing that the antibodies of the Japanese publications do not bind the ED-B domain itself. Thus the Japanese published applications do not anticipate the claims.

4

ELLIS-0003

However, if this is an erroneous interpretation of the examiner's office action, then the examiner is respectfully requested to clearly set forth the bases on which the Sekiguchi declaration is felt to be insufficient in establishing the lack of enablement of the two Japanese published applications. It is respectfully submitted that such a clear exposition is especially warranted in view of the extraordinary length of the prosecution of this application.

Should the examiner desire any clarification of any matter, she is courteously invited to telephone the undersigned who will make every effort to expeditiously provide whatever information is desired.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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Attorney Docket No.: ELLIS-0003

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